

# **Exhibit 1**

## ASP Calculation Rankles IG; Drugs To Face Dropping Reimbursement Rates?

The HHS Office of Inspector General is dissatisfied with the CMS' response to an OIG report showing that comparison of a Part B-reimbursed drug's average sales price (ASP) with its average manufacturer price (AMP) yields different results based on the calculation method used.

Because of the discrepancy, as many as 51 drug codes could have their reimbursement rate dropped in the next quarter if CMS insists on continuing to use its ASP calculation method. Alternatively, if OIG has its way, 38 drug codes could have their reimbursement rate reduced. If CMS follows a middle road by selecting drugs that meet the threshold for dropping reimbursement under both methods, only 34 drug codes would be affected.

Released May 3, the report was required by the Medicare Modernization Act (MMA) as a tool to gauge whether CMS is overpaying for Part B drugs administered in the outpatient setting. In 2005, the agency began reimbursing Part B drug providers at 106% of the ASP, using national drug code (NDC) and related sales volume data supplied by manufacturers on a quarterly basis.

MMA tasked OIG with comparing ASP to either the widely available market price (WAMP) or AMP for Part B physician-administered drugs. If OIG finds that the ASP for a product exceeds AMP by 5%, the statute directs CMS to substitute a different reimbursement rate, defined as the lesser of WAMP or 103% of AMP, beginning in the following quarter.

Accordingly, OIG's study set out to identify potentially overpaid drugs by comparing volume-weighted ASP and AMP data provided by CMS.

To set payment rates for those drugs, CMS "crosswalks" the NDC data to Healthcare Common Procedure Coding System (HCPCS) codes. The process helps CMS to assess volume-weighted ASPs for each HCPCS code.

In a March 2 report, also mandated by MMA, OIG contended that Medicare does not treat billing units consistently in its calculations – a factor that could produce incorrect volume-weighted ASPs when using the statutory equation for computing average sales price.

The earlier report, titled "Calculation of Volume-Weighted Average Sales Price for Medicare Part B Prescription Drugs," proposed an alternative formula



for ASP calculation. In contrast to this approach, CMS' method created reimbursement amounts that were either too high or too low for 60% of HCPCS codes in the first quarter of 2005, OIG claims.

OIG expounds on this criticism in its most recent report. According to "Monitoring Medicare Part B Drug Prices: A Comparison of Average Sales Prices to Average Manufacturer Prices," CMS should "modify its calculation as soon as possible."

This strategy is advised "both to ensure that reimbursement amounts are calculated correctly and to ensure that future comparisons between ASPs and AMPs yield the most meaningful results."

Concerning 364 HCPCS codes, the data derive from the first quarter of 2005, and are based on information submitted by manufacturers in the third quarter of 2004. As can be expected, however, the report's findings for drugs that exceeded the 5% threshold varied depending on which ASP metric was adopted – CMS' or OIG's.

"For 34 HCPCS codes, the volume-weighted ASPs exceeded the volume-weighted AMPs by at least 5% regardless of whether CMS' or OIG's calculation was used," the report notes. CMS' calculation method yielded another 17 codes that met the threshold, while OIG's method yielded an additional four.

OIG asserts: "If reimbursement amounts for the 51 HCPCS codes identified by CMS' calculation had been lowered to 103% of the AMP" – one of the alternative reimbursement rates – "Medicare allowances would have been reduced by an estimated \$164 mil. in 2005."

Although OIG's calculation identified a lower number of HCPCS codes meeting the 5% threshold, the report concludes that applying the AMP-based payment methodology to those codes would have generated even greater savings to Medicare: \$172 mil. in 2005.

In a January response to a draft version of the OIG report, CMS was non-committal about revisiting the ASP calculations.

The agency's response suggests it is not yet preparing to invoke its authority to adjust reimbursement rates.

"While the [HHS] Secretary has authority to adjust the ASP payment limit when certain conditions are met, we believe it is important to bear in mind timing, stabilization of ASP reporting, and other considerations [including]...future timing and frequency of ASP and AMP comparisons, effective date and duration of the rate substitution, and evaluation of the accuracy of ASP and AMP data," the agency's letter to OIG states.

CMS cautions that OIG's report was prepared during the "initial implementation phase of the ASP methodology." The agency estimates that half of OIG's estimated savings derive from "one product for which the AMP varied significantly from subsequent periods." Similarly, CMS found that more than 92% "of the estimated savings do not persist in comparing ASP and AMP data from subsequent quarters."

"Furthermore, CMS revised the first quarter payment limits for several of the identified billing codes," the agency observes.

In its counter-response, OIG challenges CMS' comments. "Although CMS indicated that our report is useful, CMS' comments on the draft report address neither the incorrect calculation nor the impact it has on the comparison between ASPs and AMPs."

"We continue to believe that CMS is calculating volume-weighted ASPs incorrectly, and that this incorrect calculation results in reimbursement amounts that are inaccurate and inconsistent with the ASP payment methodology set forth" by MMA, the report adds.

OIG states: "We acknowledge CMS' concern that our findings should be examined in light of other important considerations. However, we are unsure of what, if any, specific steps CMS plans to take as a result of the report."

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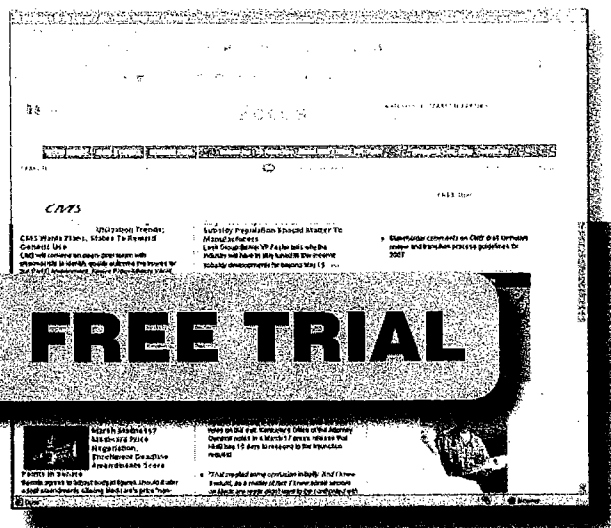
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